UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,487	04/07/2004	Jeffrey P. Whitten	532232001200	7396

25225 7590 06/20/2005

MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER	
AULAKH, CHARANJIT	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,487	WHITTEN ET AL.	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12-22,24-27 and 31-42* is/are rejected.

7)☒ Claim(s) *6-11 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. According to paper filed on April 21, 2005, the applicants have elected group I, claims 1-27 and 31-42 without traverse for further prosecution. Claims 28-30 are withdrawn from further consideration as being directed to non-elected invention.

2. Claims 1-27 and 31-42 are now pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 31-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating colon cancer using instant compounds of formula (I), does not reasonably provide enablement for ameliorating or reducing all known cell proliferative disorders and microbial titers using instant compounds or treating colon cancer using esters and prodrugs of instant compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the

breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, the state of the prior art, presence of working examples and the breadth of claims. The specification mentions on page 7 that the instant compounds interact with regions of DNA that can form quadruplexes and further teaches that molecules that interact with regions of DNA that can form quadruplexes can exert a therapeutic effect on certain cell proliferative disorders and related conditions (see page 7, lines 1-8). However, these certain proliferative disorders or related conditions are not mentioned in the specification. Furthermore, there is no teaching either in the specification or prior art that the aforementioned quadruplexes are well known in the prior art to ameliorate or reduce every known proliferative disorder or every known microbial titer. The specification only mentions using colon adenocarcinoma cell line (colo 320) with the instant compounds (see page 18). In the prior art, closely related compounds have been shown to have activity in murine P388 leukemia cell line (see JP 09221424). There are no working examples present or prior art references provided showing efficacy of instant compounds or closely related compounds in animal models or cell lines of all known cell proliferative disorders or microbial infections. There is not even a single ester or prodrug mentioned or prepared in the specification. The instant compounds of formula (I) encompasses hundreds of thousands of compounds based on the values of variables A, Z, Y, W, X, Q and R6 and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate

the efficacy of instant compounds in known animal models or cell lines of every known cell proliferative disorder and microbial infection and hence their utility for treating these disorders and infections.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 12-22, 24, 26 and 31-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the terms –esters and prodrugs--- are indefinite since specific esters and prodrugs and methods of preparing them are not defined. Also, it is not clear how the esters differ from the prodrugs?

In claim 1, the value of variables R1 and R2 defined as ---may form an optionally substituted ring--- is indefinite since the size of the ring, the number and types of heteroatoms present in the ring and the degree of saturation are not defined. Also, it is not clear whether R1 and R2 form ring together with the N atom or separately?

In claim 1, the value of variable R6 is defined only when it is present on the fused ring. How about its value when present on the first mentioned monocyclic ring for variable Y? Also, the value of variable R6 defined as ---inorganic substituent; or two adjacent R6 ---- is indefinite since meaning of inorganic substituent is not defined and furthermore, it is not clear how two adjacent R6 groups can be linked since variable Y is substituted with only one R6 group.

Claims 12-22 recites the limitation "NR1-(CR1)n-NR3R4 for the values of variables W and Z" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

In claim 24, the term ---inorganic substituents---is indefinite since these substituents are not defined.

In claim 26, compounds in table 1 are mentioned. However, table 1 is not present in the claim.

In claims 31-42, the terms –cell proliferative disorder and microbial infection--- are indefinite since specific disorders and infections are not defined.

In claims 31, 35, 37 and 40, the terms ---ameliorating or reducing --- are indefinite since the degree of amelioration or reduction (20%, 40%, 60%, 80% or 100%) are not defined and furthermore, how this amelioration or reduction is being assessed?

In claims 35 and 37, it is not clear whether the method is in vitro method or in vivo method?

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 25-27 and 31-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomita (JP 09221424).

Tomita discloses substituted Naphthyridines compounds, pharmaceutical compositions containing these compounds and a method of treating tumors using these compounds. The compound 8F 1 (see page 22) disclosed by Tomita anticipates the instant claims when A represents halogen and both Z and W represent NR1R2 in the instant compounds of formula (1).

Allowable Subject Matter

8. Claims 6-11 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

C-S. Aulakh

Charanjit S. Aulakh
Primary Examiner
Art Unit 1625